## **REMARKS**

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the remarks and enclosures herein. The Examiner is thanked for indicating that the rejection under 35 U.S.C. §103 has been withdrawn.

## APPLICANTS' CLAIM OF PRIORITY HAS BEEN PERFECTED

The Office Action indicates that certified copies of those United Kingdom applications filed on March 5, 1996, March 19, 1996, February 16, 1996, and December 5, 1996, from which the present application claims priority, have not been filed with the Patent Office as required under 35 U.S.C. §119(b). Applicants respectfully submit that required documents will be filed with the Patent Office in due course.

## THE DOUBLE PATENTING REJECTIONS ARE OVERCOME

Claims 6-20 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims of U.S. Patent No. 5,616,574, U.S. Patent 6,187,766, U.S. Patent 6,642,397, U.S. Patent Application No. 09/794,853, U.S. Patent Application No. 10/165,599 (now U.S. Patent No. 6,858,597), U.S. Patent Application No. 10/367,622, and U.S. Patent Application No. 09/572,237 (now U.S. Patent No. 6,670,353). Claims 12-16 and 19 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims of U.S. Patent Application No. 10/013,798. Applicants respectfully traverse the rejections.

However, in order to expedited allowance of the present application, enclosed herewith is a Terminal Disclaimer to each of the above-referenced applications and patents. Accordingly, the rejections are now moot and should be withdrawn.

In addition, claims 12-16 and 19 were rejected under the judicially created doctrine of obviousness-type double patenting over the claims of U.S. Patent No. 6,653,298. The rejection is respectfully traversed.

This reasoning for this rejection was originally set forth in the Office Action mailed November 14, 2003. That Office Action stated that although the conflicting claims were not

identical, they were not patentably distinct from each other because they both encompass steroid sulphamates such as estrone-3-sulphamate.

It is respectfully submitted that U.S. Patent No. 6,653,298 relates to methods for oral contraception, wherein the dosage administered to the patient is no greater than 200 mg/day per 70 kg subject. In contrast, the pharmaceutical compositions of the presently rejected claims do not specify a dosage, nor do they specify a use for the pharmaceutical composition.

It is respectfully submitted that the term "oral contraception", and the product it therefore implies, i.e., an "oral contraceptive" imparts a limitation to the claims in which it is used. In addition, the recitation of a dosage of 200 mg/day per 70 kg subject also imparts a limitation to the claims in which it is used.

The pharmaceutical compositions claimed in the present invention do not utilize the terms "oral contraception" or "oral contraceptive", nor do these claims specify a dosage of 200 mg/day per 70 kg subject. Thus, although a pharmaceutical composition <u>could be</u> used for oral contraception, and <u>could be</u> used at a dosage of 200 mg/day per 70 kg subject, a given pharmaceutical composition <u>does not have to be</u> used for oral contraception at the specified dosage.

Accordingly, it is respectfully submitted that the dosages and the intended use of oral contraception found in the claims of U.S. Patent No. 6,653,298, are patentable distinctions over the present claims. Consequently, the rejection should be withdrawn.

In view of the Terminal Disclaimer enclosed herewith, and the remarks herein, reconsideration and withdrawal of the double patenting rejections is respectfully requested.

## REQUEST FOR FURTHER INTERVIEW & CONCLUSION

If any issue remains as an impediment to allowance, a further interview is respectfully requested, with the Examiner invited to contact the undersigned telephonically to arrange a mutually convenient time and manner therefore.

In view of the remarks and attachments herewith, the application is in condition for allowance. Favorable reconsideration of the application, and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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